Remarks

Claims 73-115 were pending in the subject application. By this amendment, applicants have canceled Claims 80-91, 95-97, 101-103, 107-109 and 113-115 without prejudice or disclaimer, and amended claims 73-75. Accordingly, after entry of this amendment, Claims 73-79, 92-94, 98-100, 104-106 and 110-112 will be pending and under examination.

Applicants maintain that the amendments to claims 73-75 do not raise an issue of new matter. Support for the claim amendments can be found in the previous version of the claims.

Applicants maintain that replacement Figures 3A-3C, 5A-5D, 6, 7, and 9 attached hereto as **Exhibit 1** do not raise an issue of new matter.

Accordingly, applicants respectfully request that the Amendment be entered.

Objections to the Drawings

In response to the Notice of Draftperson's Patent Drawing Review, a copy of which is attached hereto as **Exhibit 2**, applicants have replaced previous Figures 3A-3C, 5A-5D, 6, 7, and 9 with replacement Figures 3A-3C, 5A-5D, 6, 7, and 9 attached hereto as **Exhibit 1**. Applicants note that the previous version of Figure 9 occupied two drawing sheets. The spacing of the figure has been condensed so that replacement Figure 9 fits on one drawing sheet.

Rejections under 35 U.S.C. §101 and 35 U.S.C. §112, first paragraph

On page 3 of the Office Action, the Examiner rejected claims 73-115 under 35 U.S.C. §101 and 35 U.S.C. §112, first paragraph as allegedly lacking utility and enablement (i.e., one skilled in the art would allegedly not know how to use the claimed

invention). The Examiner stated in part that the instant invention is not considered to have a specific and/or substantial utility because the specification fails to establish that the polynucleotide sequences as claimed encode a protein which is a member of the glucose transporter/sensor/receptor family as shown by structural and/or functional properties.

In a response filed on December 12, 2002, applicants maintained that the claimed invention has utility as a marker of hyperglycemia and diabetes, and in the diagnosis of breast cancer. Applicants noted that the specification discloses that the livers and placentas of diabetic and hyperglycemic animals show a 2 to 3 fold upregulation of the expression of the claimed nucleic acids, as compared to normal animals (page 39, lines 12-30). Thus, applicants maintained that the claimed nucleic acids have specific, credible, and substantial utility as a marker of diabetes or hyperglycemia, independently of a description of the biological activity of the nucleic acids or the polypeptides encoded by the nucleic acids; i.e. independently of GLUTx functioning as a glucose transporter. In addition, applicants further noted that the specification discloses that GLUTx protein is expressed in mammary tumors but not in normal mammary tissue (page 38, line 30 through page 39, line 11). Accordingly, applicants maintained that the subject invention also has utility for the detection of breast cancer. Applicants further noted that an applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement (MPEP 2107 II. (B) (1) (ii)).

In response, on page 7 of the instant Office Action, the Examiner asserted that the 2-3 fold up-regulation of the claimed nucleic acid sequences in the livers of diabetic and hyperglycemic animals is not specific, since the instant specification clearly discloses the expression of GLUTx mRNA in a variety of tissues including brain, liver and testis of both normal and diabetic rats. As a further response, applicants direct the

Examiner's attention to page 39, lines 21-25, where it is indicated that the observed 2-3 fold upregulation of mRNA expression was observed in the liver and placenta, but not in the testis or brain, which had the same levels as in normal animals. Thus, diabetic and hyperglycemic animals show a 2 to 3 fold upregulation of GLUTx mRNA expression that is specific for the liver and placenta, in comparison to the testis and brain where mRNA expression remains at normal levels.

The Examiner further asserted that the use of GLUTx antibodies to identify breast cancer is not specific since GLUTx protein was also found in testis, heart, fat, liver, diaphragm and soles muscles in GLUT4 null and wild type mice. In response, applicants respectfully point out that the presence or absence of GLUTx protein in non-breast tissue is not relevant for the diagnosis of breast cancer. What is relevant, and specific, is the absence of GLUTx protein in normal mammary tissue and the presence of GLUTx protein in mammary tumor, as determined using Western blot analysis (see Specification, page 39, lines 8-11). Applicants also provide the amino acid sequence of the last 11 amino acids of the carboxy-terminus of the GLUTx protein that was used to generate the antibody that was used to detect the presence of GLUTx protein in the mammary tumor (see Specification, page 38, line 30, through page 39, line 1). The skilled artisan would know how to generate an antibody to the specified amino acid sequence and how to use the antibody to determine whether a mammary tissue sample contained GLUTx protein, where the presence of GLUTx protein in the mammary tissue is an indication that the subject has breast cancer.

Based on the above discussion, applicants maintain that the claimed invention fulfills the requirement of 35 U.S.C. §101 as having a "specific, substantial, and credible use ..." (MPEP 2164.07). Further, applicants maintain that the claimed invention fulfills the requirements of 35 U.S.C. §112, first paragraph, in that since the claimed invention is supported by a credible asserted utility, the skilled artisan would

know how to use the claimed invention. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejection under 35 U.S.C. §112, First Paragraph

On page 8 of the Office Action, the Examiner rejected Claims 80-91, 95-97, 101-103, 107-109 and 113-115 for failing to meet the written description requirement of 35 U.S.C. §112, first paragraph.

Applicants have hereinabove canceled Claims 80-91, 95-97, 101-103, 107-109 and 113-115, thereby rendering this rejection moot.

Rejection under 35 U.S.C. §112, Second Paragraph

On page 11 of the Office Action, the Examiner rejected Claims 73-115 under 35 U.S.C. §112, second paragraph. The Examiner stated that there is insufficient antecedent basis for "the nucleic acid" in line 3 of each of Claims 73-75.

Applicants have hereinabove amended independent Claims 73-75 to delete the phrase "the nucleic acid" in line 3 of each of claim and to recite: "An isolated nucleic acid comprising at least 1362 nucleotides and consisting essentially of a nucleic acid encoding a polypeptide comprising consecutive amino acids having the sequence set forth in SEQ ID NO:.. ." Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejections under 35 U.S.C. §102(b)

On page 11 of the Office Action, the Examiner rejected Claims 81-87, 82-91 and 114-115 under 35 U.S.C. §102(b) as anticipated by Lee et al. (1998 and 1995, of record).

Applicants have hereinabove canceled Claims 81-91 and 114-115, thereby

rendering this rejection moot.

Supplemental Information Disclosure Statement

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the five references which are listed on form PTO/SB/08A-B (2 pages) (**Exhibit 3**) and attached hereto as **Exhibit 4**.

Applicants are submitting the subject Information Disclosure Statement pursuant to 37 C.F.R. §1.97(c)(2) before the mailing of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application. A check for $180.00 is enclosed to cover the fee for submitting an Information Disclosure Statement pursuant to 37 C.F.R. §1.97(c)(2).

Conclusion

In light of the claim amendments and remarks made hereinabove, applicants respectfully request withdrawal of the objections and rejections set forth in the March 11, 2003 Office Action and passage of the pending claims to allowance. If there are any minor matters that would prevent allowance of the claims, applicants request that the Examiner contact the undersigned attorney.

A check for $180.00 is enclosed to cover the fee for submitting an Information Disclosure Statement. No other fee is deemed necessary in connection with the submission of this Amendment. However, if there are any unanticipated fees required to maintain the pendency of this application, the PTO is authorized to withdraw those fees from Deposit Account 01-1785. Overcharges may also be credited to Deposit Account 01-1785.

Respectfully submitted,

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